PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Applicant | : | Sean T. O'Mara |
| Application No. | : | 10/086,940 |
| Filed | : | March 1, 2002 |
| For | : | INTUBATION DEVICE AND METHOD |

| | | |
|---|---|---|
| Examiner | : | Aaron J. Lewis |
| Art Unit | : | 3743 |
| Docket No. | : | 920070.417 |
| Date | : | April 30, 2007 |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.131

I, Dr. Sean T. O'Mara, do hereby declare that:

1. I am the inventor of the invention described and claimed in U.S. Patent Application Serial Number 10/086,940.

2. The present application was filed on March 1, 2002, and claims priority to U.S. Provisional Application No. 60/273,795, filed March 5, 2001.

3. I have reviewed the Office Action mailed June 27, 2006, the Office Action mailed December 28, 2006, and the Advisory Action mailed March 5, 2007, in the subject application. The Office Action mailed December 28, 2006, rejected claims 66-71 and 73-78 based in whole or in part on the disclosure of U.S. Patent No. 6,820,614 issued to Bonutti on November 23, 2004.

4. In the Advisory Action the Examiner indicated insufficient detail was provided regarding the dates of due diligence in a prior declaration I submitted. In response, I reviewed my records pertaining to my invention in more detail. My more detailed review of my records refreshed my memory.

5. Prior to the December 2, 2000 filing date of Bonutti, and while in the United States, I reduced to practice the method of claim 66, a method comprising "inserting an intubation-tube placement device, secured to an intubation tube, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding the intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords."

6. Prior to the December 2, 2000 filing date of Bonutti, and while in the United States, I reduced to practice the method of claim 73, a method comprising "inserting an intubation-tube placement device having an exploratory portion shaped to prevent the intubation-tube placement device from perforating an internal body structure during insertion, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding an intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords."

7. Exhibit A attached hereto is a true and correct copy of a portion of an invention disclosure document prepared in the United States by me. Exhibit A bears a date and I have seen the date on the document. The date is prior to the December 2, 2000, filing date of Bonutti. The date and other information, as well as my signature, have been removed from the copy of the document submitted herewith, which I understand is permissible under Patent Office practice.

8. Exhibit A shows the reduction to practice of the method of claim 66, a method comprising "inserting an intubation-tube placement device, secured to an intubation tube, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding the intubation tube along the intubation-tube placement device such that the intubation tube follows

the intubation-tube placement device through the patient's vocal cords." See the detail in Sections 10, and 14(a) and (b) and the Figure of Section 8.

9. In particular, the references in Section 14 to "this device" refer to an actual working model having a tactile-accentuator, and the references in Section 10 (B), (C) and (E) to sharing this device refer to confidential demonstrations of the actual working model on an anatomically correct manikin and while in the United States. Prior to the demonstrations referred to in Sections 10 (B), (C) and (E), I tested the actual working model on patients in the United States. Thus, Exhibit A shows the reduction to practice of the limitations in claim 66 prior to the December 2, 2000, filing date of Bonutti.

10. One of the persons to whom I demonstrated the working model and, using an anatomically correct manikin, the method comprising "inserting an intubation-tube placement device, secured to an intubation tube, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding the intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords," was Brian O'Mara. I understand Brian O'Mara has executed a declaration which is being concurrently submitted herewith.

11. Exhibit A shows the reduction to practice of the method of claim 73, a method comprising "inserting an intubation-tube placement device having an exploratory portion shaped to prevent the intubation-tube placement device from perforating an internal body structure during insertion, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding an intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords." See the detail in Sections 10, and 14(a) and (b) and the Figure of Section 8.

12. In particular, the references in Section 14 to "this device" refer to an actual working model having an exploratory portion shaped to prevent the intubation-placement device from perforating an internal body structure and a tactile-accentuator, and the references in

Section 10 (B), (C) and (E) to sharing this device refer to confidential demonstrations of the actual working model on an anatomically correct manikin and while in the United States. Prior to the demonstrations referred to in Sections 10 (B), (C) and (E), I tested the actual working model on patients in the United States. Thus, Exhibit A shows the reduction to practice of the limitations in claim 73 prior to the December 2, 2000, filing date of Bonutti.

13. One of the persons to whom I demonstrated the working model and, using an anatomically correct manikin, the method comprising "inserting an intubation-tube placement device having an exploratory portion shaped to prevent the intubation-tube placement device from perforating an internal body structure during insertion, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding an intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords," was Brian O'Mara. I understand Brian O'Mara has executed a declaration which is being concurrently submitted herewith.

14. The date on Exhibit A is within six months of the December 2, 2000, filing date of Bonutti and the March 5, 2001 filing date of the provisional application. The dates of the demonstrations referred to in Section 10 (B), (C) and (E) are prior to the December 2, 2000 filing date of Bonutti and within one year of the March 5, 2001 filing date of the provisional application.

15 I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATE: April 30, 2007

Sean T. O'Mara

# DEPARTMENT OF THE ARMY
# UNITED STATES OF AMERICA

## INVENTION DISCLOSURE

(THIS FORM AND ACCOMPANYING DRAWING AND DESCRIPTION SHEETS ARE TO BE COMPLETED FOR EACH INVENTION PROMPTLY FORWARDED TO THE PATENT ACTIVITY)

PATENT ACTIVITIES . DOCKET NO

ASSIGNED TO:

SHORT TITLE OF INVENTION

| FULL NAME(S) OF INVENTOR(S) (FIRST) (MIDDLE INITIAL) (LAST) | HOME ADDRESS(ES) | (DUTY) TEL. NO. AREA CODE |
|---|---|---|
| 1. Sean T. OMara | | |
| 2. | | |
| 3. | | |

**INFORMATION AND DATES CONCERNING THIS INVENTION**

NEEDED IN THE EVENT OF A CONTEST OF PRIORITY OF INVENTION IN THE U.S. PATENT AND TRADEMARK OFFICE. ALL RECORDS CITED SHOULD BE DATED AND SIGNED BY TWO UNDEPENDENT WITNESSES WHO HAVE READ AND UNDERSTOOD THE MATERIAL

ON WHAT DATE DID YOU FIRST THINK OF THIS INVENTION (WHAT RECORDS SHOW THIS?)
(4) None

GIVE DATE OF AND IDENTIFY EARLIEST SKETCH OR DRAWING

WHEN/WHERE AND TO WHOM DID YOU MAKE THE FIRST DISCLOSURE TO OTHERS OF THE INVENTION
(5)

DESCRIBE DETAILS OF ANY WORK OR TESTS DONE TO PRODUCE OR OPERATE THE INVENTION GIVE DATES AND WITNESSES (USE OTHER PAGES IF NECESSARY)
(7) See attached marked 7

DESCRIBE AND GIVE DATES OF ANY OTHER SKETCHES, DRAWINGS, OR REPORTS PERTINENT TO THIS INVENTION
(8) See attached marked 8

**USE, SALE OR PUBLICATION**

NEEDED TO ESTABLISH THE DATE OF ANY PRINTED PUBLICATION, PUBLIC USE OR SALE. SINCE NO PATENT APPLICATION MAY BE FILED AFTER

IF INVENTION HAS BEEN SOLD OR USED FOR PROFIT-WHEN AND TO WHOM DISCLOSED OR WHEN AND HOW USED?
No - never has

HAS A DESCRIPTION OF THIS INVENTION BEEN MADE AVAILABLE TO PERSONS OUTSIDE THE ARMY? (WRITTEN OR ORAL) IF SO, HOW AND WHEN AND WAS USE RESTRICTED?
(10) See attached marked 10

**POTENTIAL MARKET**

NEEDED FOR POSSIBLE MARKETING INVESTIGATIONS AND AS AN AID TO POTENTIAL

DESCRIBE ANY POTENTIAL OR EXISTING MARKET FOR SALE OR LICENSE OF THIS INVENTION
(11)
A. GOVERNMENT: Military Hospitals, Clinics, Aid Stations, Ambulances, Combat medics
B. COMMERCIAL: Hospitals, Ambulances/EMS systems, worldwide
C. IDENTIFY ANY KNOWN FIRMS OR VENDORS WHO MAY BE INTERESTED IN THE INVENTION:
Too numerous to list.

**CONTRACT INFORMATION**

A DETERMINATION OF RIGHTS IN THIS INVENTION WILL BE NECESSARY. (SEE AR 27-60)

IF THIS INVENTION WAS FIRST CONCEIVED OR CONSTRUCTED IN CONNECTION WITH:
(12)
A. MY DUTIES AS A GOVERNMENT EMPLOYEE
(B.) MY WORK UNRELATED TO MY DUTIES AS A GOVERNMENT EMPLOYEE (PRIVATE, OFF DUTY ACTIVITIES)
C. MY DUTIES AS A GOVERNMENT EMPLOYEE & WORKING WITH A CONTRACTOR
D. NEITHER A, B, OR C, EXPLAIN

**FOREIGN FILING CONSIDERATION**

NEEDED TO DETERMINE THE POTENTIAL WORLDWIDE USE FOR THE INVENTION.

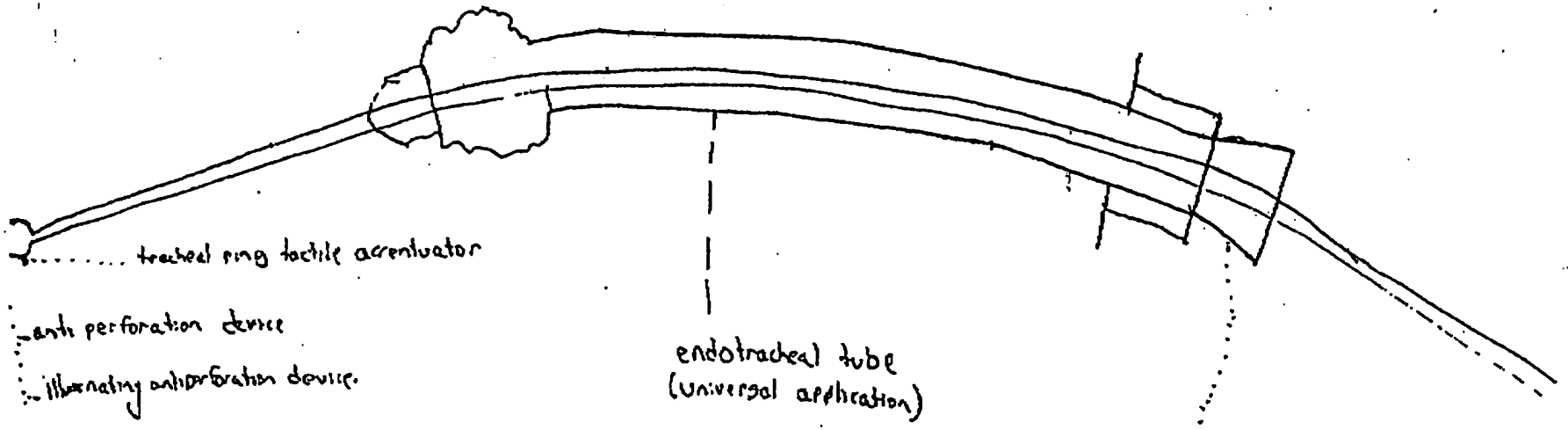
INDICATE THE POTENTIAL FOR USING THIS INVENTION IN FOREIGN COUNTRIES
(13)
☐ POOR
☐ GOOD
☒ EXCELLENT

**SECURITY CLASSIFICATION**

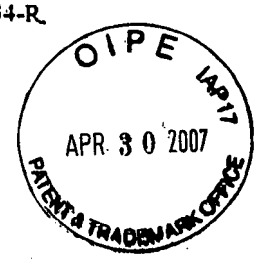
PLEASE INDICATE THE SECURITY CLASSIFICATION IF KNOWN
(13A)
☐ CLASSIFIED LEVEL
☒ UNCLASSIFIED
☐ CLASSIFICATION UNKNOWN

DA FORM 4734-R, 1 OCT 1978

USAPA V1.00



Addendum to DA form 4734-R
(7)




(10)... I have shared this product/device to the following non-Army personnel all under restricted/confidential terms. All were advised of this device's restricted disclosure and confidentiality. Each verbally consented to keep the device's design and application confidential.

E. Mr. Brian Omara Vienna, VA 22180.

(14) A
See attached sketch
The device functions to insert, introduce and guide an Endotracheal Tube (ETT) into a patient's trachea more easily safely and successfully than other current devices and methods presently available. This device is not only intended for and beneficial as an initial device to intubate all patients on the first attempt but also as a "rescue device" for difficult intubation patients as well.

(14) B
This device's composition of lower coefficient of friction than other devices (somewhat similar in design or intended objective) makes this device easier to use with much less resistance. Furthermore, this device incorporates on its proximal insertion end an "antiperforation device" (which is the intended subject of its own patentable application) to dramatically reduce the risk of perforation that other products/devices currently available are limited by and vulnerable to. My device incorporates existing and universal endotracheal tubes to it thereby allowing its use as a complete unit to greatly improve ease of use, ability to hold, guide, manipulate and ultimately introduce the device endotracheally.
Currently all other devices are designed to have the ET tube threaded over the introducer/stylett only after the device has been endotracheally placed. Currently existing devices provide the intubator with poor control. Only my device uniquely combines both the introducer/stylett/catheter with the ET tube into a single intubating unit to overcome this one major limitation common to all other existing devices. The benefit of this simplified one unit design represents a significant enhancement in ease and effectiveness of intubating. Having the intubating physician grasp the ET tube already surrounding the stylett/catheter and affixed to the same by a precisely engineered retention device uniquely provides the intubating physician unsurpassed control and purchase of the stylett/catheter they are attempting to advance toward the objective anatomy. My device is also unique from presently existing devices in its primary use as an initial intubation product for all initial intubations where oral intubations are not otherwise contraindicated. In so doing my device boldly departs from the standard conventional but inferior approach of initially attempting

to insct the larger. more cumbersome and view obscuring ET tube. through the cords initially without first passing a stylett/catheter or introducer.

The antiperforation device on my product further incorporates. at least in this application. a tracheal ring accentuator device (also the intended subject of a future patentable device) to amplify the tactile perception of tracheal cardiage rings lining the patient's trachea as an aid in confirming correct placement so critical in intubation

The product's thinner diameter (body 1/8" and proximal head 3/16") allows for less resistance and easier introduction with less obscuring of the intubator's field of vision. It also reduces the risk of perforation (to either normally present tissue structures or abnormal tissue from tumor. inflammation. hematoma or other pathology) with superior insertion properties. The thinner design also provides the ability to intubate with small pediatric endotracheal tubes (currently no device exists to introduce ET (endotracheal) tubes of 6.0 mm and below or for children age eight and younger) and does so with less costs. Additionally my device is dramatically more affordable with an estimated production expense of less than one dollar for both product supply and assembly. It is disposable where most others are not thereby obviating the need for costly decontamination. This device is intended for use as an initial and primary intubating device for all attempted intubations and will greatly improve the success rate of initial attempts at intubation. Its unique design incorporating an endotracheal tube as a complete unit allows for faster introduction of the ET tube within the trachea and permits instantaneous (technique conversion to "rescue intubation" when the patient's vocal cords can not be visualized. This convenient ability to convert techniques allows for more rapid and successful intubation by eliminating the need for having to withdraw the laryngoscope. ventilating the patient back up. re-executing laryngoscopy and then introducing another rescue device toward the objective anatomy.

Another version of my device may be used as part of an intubation system which is completely free of the need for decontamination and completely disposable. This version of my device achieves this by eliminating the current reliance on illumination from costly and problematic conventional laryngoscopes required by all other presently existing devices. This version of my device with only modest added expense incorporates on its most proximal end (the end inserted through the cords) an illuminating light source/lightbulb. This will not only provide the added anti perforation characteristics of the non illuminating version but will obviate the need for reliance upon lighted laryngoscope blades which are expensive and costly to maintain as well as potential sources of contagion. The light source on this version of the product is connected distally to a battery source and may be reused as a cost saving feature to the system while the rest of the device and plastic non illuminating laryngoscope blade are fully disposable. This second version permits rapid and numerous intubations of different patients limited only by the number of disposable devices and ET tubes available without any reliance on need for decontamination/sterilization processes currently now required. While compared to the non-illuminating version the illuminating feature of this version will add modest costs with a estimated manufacturing costs of still only approximately five dollars. It will still be disposable and ultimately considerably cheaper than presently existing intubation methods especially when the cost saved from avoiding sterilizing processes are considered.

In short. my device is simple to use. more effective in achieving first attempt intubations than other presently existing devices. completely disposable. with less risk for iatrogenic insult or injury and furthermore secures intubations with these added benefits more affordably than present devices. It has the potential. with time. for completely supplanting how all intubations are presently done with the widest of possible applications from the setting of controlled intubations in the OR. to the emergent intubation of an Emergency Room or field EMS setting. Its ease of use. and capacity for non-reliance on conventional laryngoscope blades which require sterilization. makes it ideally suited for the military combat medic. Safe intubations can now be quickly, easily and affordably obtained by medical personnel with even limited training through this device. It is likely with time that a method for safely and effectively achieving endotracheal intubations could be developed with this device alone through its blind but careful insertion into the patients oral pharanx. It is clear this device has great potential and its warm reception from experienced physicians supports its predicted contributions in improving the paramountly important procedure of endotracheal intubation.

# DEPARTMENT OF THE ARMY
# UNITED STATES OF AMERICA
## INVENTION DISCLOSURE

(DRAWING AND DESCRIPTION SHEET)

PATENT ACTIVITIES DOCKET NO

(14) PROVIDE THE FOLLOWING INFORMATION CONCERNING THE DISCLOSED INVENTION AND IN THE INDICATED SEQUENCE:

A. SPECIFICALLY DESCRIBE THE INVENTION AND ITS OPERATION. YOU MAY USE AND ATTACH COPIES OF SKETCHES, PRINTS, PHOTOGRAPHS, PAPERS AND ILLUSTRATIONS, WHICH SHOULD BE SIGNED, WITNESSED, AND DATED. USE NUMBERS AND DESCRIPTIVE NAMES IN DESCRIPTIONS AND DRAWINGS.

B. STATE THE ADVANTAGES OF THE INVENTION OVER PRESENTLY KNOWN DEVICES, SYSTEMS, OR PROCESSES.

C. DISCUSS THE PROBLEMS WHICH THE INVENTION IS DESIGNED TO SOLVE, REFERRING TO ANY PRIOR INVENTION OF A SIMILAR NATURE WITH WHICH YOU MAY BE FAMILIAR.

D. LIST ALL KNOWN AND OTHER POSSIBLE USES FOR THE INVENTION.

E. LIST THE FEATURES OF THE INVENTION THAT ARE BELIEVED TO BE NOVEL.

USE AS MANY OF THESE SHEETS AS NECESSARY AND ATTACH TO COMPLETED INVENTION DISCLOSURE

See attached marked 14 (A) (B). ((B) incorporates C-E as well.

SIGNATURE(S) AND ORGANIZATION OF INVENTOR(S) (USE INK) DATE: THE DESCRIBED INVENTION HAS BEEN WITNESSED READ AND UNDERSTOOD BY: DATE:

(15) _____ (16) _____ _____

ORGANIZATION

(16) _____ (19) _____ _____

ORGANIZATION

(17) _____ (20) _____ _____

ORGANIZATION

NOTE: THIS FORM AND ANY OMITTED INFORMATION BECOMING AVAILABLE AT A LATER TIME SHOULD BE FORWARD TO:
HQDA CHIEF, INTELLECTUAL PROPERTY DIV, OFFICE OF THE JUDGE ADVOCATE GENERAL DEPT. OF THE ARMY WASHINGTON, D.C., 20310
DARCOM ATTN: PATENT COUNSEL; OR CHIEF OF ENGINEERS ATTN: PATENT COUNSEL

REVERSE OF DA FORM 4734-R, 1 OCT 1978



USAPA V1.00

# INVENTION RIGHTS QUESTIONNAIRE

For use of this form, see AR 27-60; the proponent agency is OTJAG

**READ THE INSTRUCTIONS BELOW BEFORE COMPLETING THIS FORM**

o Under Executive Order 10096, 23 January 1950, and AR 27-60, whenever an invention is made by a military or civilian employee of the Department of the Army, it is necessary to determine the rights in the invention as between the Government and the inventor. There are three ways in which rights may be determined:

– The inventor may be entitled to all rights and the Government to none (and hence the inventor need sign no document giving any rights to the Government);

– The Government may be entitled to a license permitting it to use or practice the invention and the inventor entitled to all other rights (and hence the inventor signs a license to the Government);

– The Government may be entitled to all rights and the inventor to none (and hence the inventor signs an assignment to the Government).

o Separate and distinct from the determination of rights, and even though it may appear that the inventor is entitled to all rights in the invention, the inventor may sign a license permitting the Government to use and practice the invention in return for which the Government will prosecute an application for a patent on the invention at no expense to the inventor, provided the Government is sufficiently interested in the invention.

o If the inventor desires voluntarily to assign all rights in the invention to the Government, he may complete PART A below. The remaining questions need not be answered.

o If the inventor does not desire to voluntarily assign all rights in the invention to the Government, it is necessary that all questions be answered completely. The determination of the rights in the invention depends upon the facts and circumstances under which the invention was made. In almost every case a failure to provide sufficient information works to the disadvantage of the inventor. If additional space is needed to fully answer any question, an attached sheet will be used. Many questions may be answered by a check mark; however, every question must be answered even if the appropriate answer is "No", "None", or "NA"(not applicable). Print or type all answers.

**SECTION I - TO BE COMPLETED BY THE INVENTOR**

**PART A - BASIC DATA**

1. BRIEF TITLE OF INVENTION

2. NAME OF INVENTOR

3. GRADE AT TIME INVENTION WAS MADE

4. JOB TITLE AT TIME INVENTION WAS MADE

5. COMPLETE NAME OF ORGANIZATION AT TIME INVENTION WAS MADE *(Include, as applicable, unit, section, branch, division, department, laboratory, post, camp, station, branch of Army)*

6. I DESIRE TO ASSIGN TO THE UNITED STATES GOVERNMENT THE ENTIRE RIGHT, TITLE AND INTEREST IN AND TO THE [illegible]IED INVENTION. *(Signature below is necessary only if assigning rights of invention to the Government. The remainder of this form is not necessary if you sign below.)*

a. SIGNATURE OF INVENTOR

b. DATE

DA FORM 2871-R, APR 93

REPLACES DA FORM 2871, JAN 85 WHICH IS OBSOLETE

USAPPC V2.00

EXPRESS MAIL NO. EV889152987US


PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|---|---|---|
| Applicant | : | Sean T. O'Mara |
| Application No. | : | 10/086,940 |
| Filed | : | March 1, 2002 |
| For | : | INTUBATION DEVICE AND METHOD |

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| Examiner | : | Aaron J. Lewis |
| Art Unit | : | 3743 |
| Docket No. | : | 920070.417 |
| Date | : | April 23, 2007 |

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

WITNESS DECLARATION OF BRIAN O'MARA UNDER 37 CFR 1.131

I, Brian O'Mara, do hereby declare that:

1. I am the brother of Sean T. O'Mara, the inventor of the invention described and claimed in U.S. Patent Application Serial Number 10/086,940.

2. I understand that Exhibit A attached hereto is a true and correct copy of a portion of an invention disclosure document prepared in the United States by Sean T. O'Mara. I have reviewed Section 10 (E) of Exhibit A. Section 10 (E) of Exhibit A bears a date and I have seen the date on the document. The date is prior to December 2, 2000. The date and other information have been removed from the copy of the document submitted herewith, which I understand is permissible under Patent Office practice.

3. Sean T. O'Mara demonstrated to me, using a working model of an intubation-tube placement device and an anatomically correct manikin, the method comprising "inserting an intubation-tube placement device, secured to an intubation tube, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device

through the patient's vocal cords; and axially sliding the intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords." My recollection of the date of the demonstration is consistent with the date in Section 10 (E) of Exhibit A, which is prior to December 2, 2000.

4. Sean T. O'Mara demonstrated to me, using the working model of an intubation-tube placement device and the anatomically correct manikin referred to above in paragraph 3, the method comprising "inserting an intubation-tube placement device having an exploratory portion shaped to prevent the intubation-tube placement device from perforating an internal body structure during insertion, into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator device coupled to the intubation-tube placement device; forcing the intubation-tube placement device through the patient's vocal cords; and axially sliding an intubation tube along the intubation-tube placement device such that the intubation tube follows the intubation-tube placement device through the patient's vocal cords." My recollection of the date of the demonstration is consistent with the date in Section 10 (E) of Exhibit A, which is prior to December 2, 2000.

5. I have reviewed the sketch in Section 8 of Exhibit A. This sketch is consistent with my memory of the working model of an intubation-tube placement device referred to in paragraphs 3 and 4 above.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATE: 4/23/07

Brian O'Mara

941502_1.DOC

# DEPARTMENT OF THE ARMY
# UNITED STATES OF AMERICA

## INVENTION DISCLOSURE

(THIS FORM AND ACCOMPANYING DRAWING AND DESCRIPTION SHEETS ARE TO BE COMPLETED FOR EACH INVENTION PROMPTLY FORWARDED TO THE PATENT ACTIVITY)

PATENT ACTIVITIES . DOCKET NO

ASSIGNED TO:

SHORT TITLE OF INVENTION

| FULL NAME(S) OF INVENTOR(S) (FIRST) (MIDDLE INITIAL) (LAST) | HOME ADDRESS(ES) | (DUTY) TEL. NO. AREA CODE |
|---|---|---|
| (1) Sean T. O'Mara | | |
| (2) | | |

**INFORMATION AND DATES CONCERNING THIS INVENTION**

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ON WHAT DATE DID YOU FIRST THINK OF THIS INVENTION (WHAT RECORDS SHOW THIS?)
(5) None

GIVE DATE OF AND IDENTIFY EARLIEST SKETCH OR DRAWING

WHEN/WHERE AND TO WHOM DID YOU MAKE THE FIRST DISCLOSURE TO OTHERS OF THE INVENTION
(6)

DESCRIBE DETAILS OF ANY WORK OR TESTS DONE TO PRODUCE OR OPERATE THE INVENTION GIVE DATES AND WITNESSES (USE OTHER PAGES IF NECESSARY)
(7) See attached marked 7

DESCRIBE AND GIVE DATES OF ANY OTHER SKETCHES, DRAWINGS, OR REPORTS PERTINENT TO THIS INVENTION
(8) See attached marked 8

**USE, SALE OR PUBLICATION**

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IF INVENTION HAS BEEN SOLD OR USED FOR PROFIT-WHEN AND TO WHOM DISCLOSED OR WHEN AND HOW USED?
No - never has

HAS A DESCRIPTION OF THIS INVENTION BEEN MADE AVAILABLE TO PERSONS OUTSIDE THE ARMY? (WRITTEN OR ORAL) IF SO, HOW AND WHEN AND WAS USE RESTRICTED?
(10) See attached marked 10

**POTENTIAL MARKET**

NEEDED FOR POSSIBLE MARKETING INVESTIGATIONS AND AS AN AID TO POTENTIAL

DESCRIBE ANY POTENTIAL OR EXISTING MARKET FOR SALE OR LICENSE OF THIS INVENTION
(11)
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B. COMMERCIAL: Hospitals, Ambulances/EMS systems, worldwide
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**CONTRACT INFORMATION**

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B. MY WORK UNRELATED TO MY DUTIES AS A GOVERNMENT EMPLOYEE (PRIVATE, OFF DUTY ACTIVITIES)
C. MY DUTIES AS A GOVERNMENT EMPLOYEE & WORKING WITH A CONTRACTOR
D. NEITHER A, B, OR C, EXPLAIN

**FOREIGN FILING CONSIDERATION**

NEEDED TO DETERMINE THE POTENTIAL WORLDWIDE USE FOR THE INVENTION.

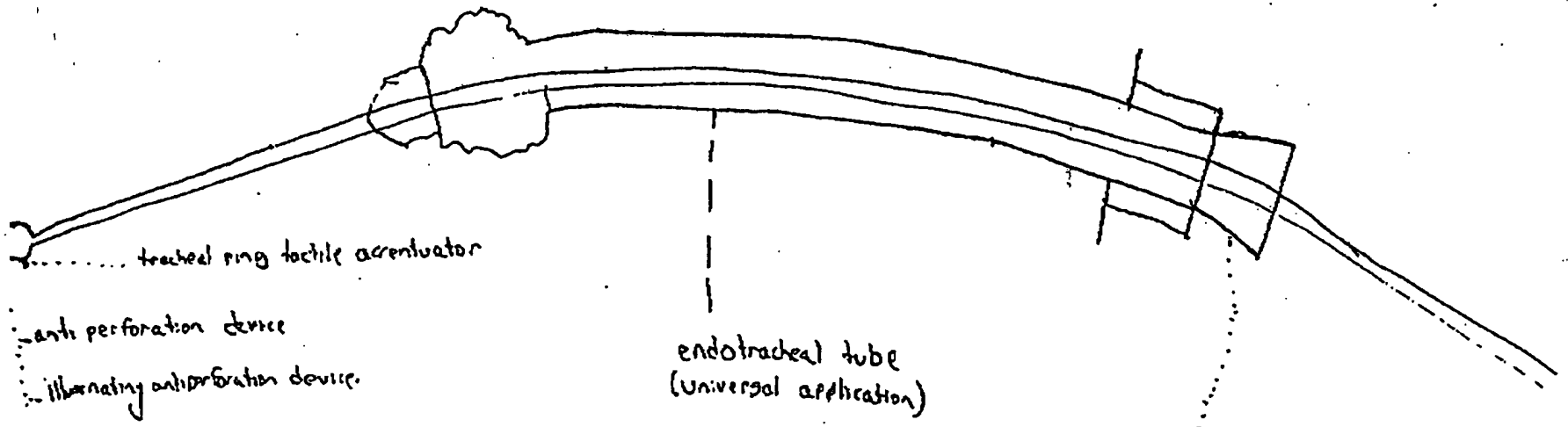
INDICATE THE POTENTIAL FOR USING THIS INVENTION IN FOREIGN COUNTRIES
(13)
☐ POOR
☐ GOOD
☒ EXCELLENT

**SECURITY CLASSIFICATION**

PLEASE INDICATE THE SECURITY CLASSIFICATION IF KNOWN
(13A)
☐ CLASSIFIED LEVEL
☒ UNCLASSIFIED
☐ CLASSIFICATION UNKNOWN

DA FORM 4734-R, 1 OCT 1978

USAPA V1.00



(10)... I have shared this product/device to the following non-Army personnel all under restricted/confidential terms. All were advised of this device's restricted disclosure and confidentiality. Each verbally consented to keep the device's design and application confidential.

E. Mr. Brian Omara Vienna, VA 22180.

(14) A
See attached sketch
The device functions to insert, introduce and guide an Endotracheal Tube (ETT) into a patient's trachea more easily safely and successfully than other current devices and methods presently available. This device is not only intended for and beneficial as an initial device to intubate all patients on the first attempt but also as a "rescue device" for difficult intubation patients as well.

(14) B
This device's composition of lower coefficient of friction than other devices (somewhat similar in design or intended objective) makes this device easier to use with much less resistance. Furthermore, this device incorporates on its proximal insertion end an "antiperforation device" (which is the intended subject of its own patentable application) to dramatically reduce the risk of perforation that other products/devices currently available are limited by and vulnerable to. My device incorporates existing and universal endotracheal tubes to it thereby allowing its use as a complete unit to greatly improve ease of use, ability to hold, guide, manipulate and ultimately introduce the device endotracheally.
Currently all other devices are designed to have the ET tube threaded over the introducer/stylett only after the device has been endotracheally placed. Currently existing devices provide the intubator with poor control. Only my device uniquely combines both the introducer/stylett/catheter with the ET tube into a single intubating unit to overcome this one major limitation common to all other existing devices. The benefit of this simplified one unit design represents a significant enhancement in ease and effectiveness of intubating. Having the intubating physician grasp the ET tube already surrounding the stylett/catheter and affixed to the same by a precisely engineered retention device uniquely provides the intubating physician unsurpassed control and purchase of the stylett/catheter they are attempting to advance toward the objective anatomy. My device is also unique from presently existing devices in its primary use as an initial intubation product for all initial intubations where oral intubations are not otherwise contraindicated. In so doing my device boldly departs from the standard conventional but inferior approach of initially attempting

to insert the larger, more cumbersome and view obscuring ET tube, through the cords initially without first passing a stylett/catheter or introducer.

The antiperforation device on my product further incorporates, at least in this application, a tracheal ring accentuator device (also the intended subject of a future patentable device) to amplify the tactile perception of tracheal cardilage rings lining the patient's trachea as an aid in confirming correct placement so critical in intubation

The product's thinner diameter (body 1/8" and proximal head 3/16") allows for less resistance and easier introduction with less obscuring of the intubator's field of vision. It also reduces the risk of perforation (to either normally present tissue structures or abnormal tissue from tumor, inflammation, hematoma or other pathology) with superior insertion properties. The thinner design also provides the ability to intubate with small pediatric endotracheal tubes (currently no device exists to introduce ET (endotracheal) tubes of 6.0 mm and below or for children age eight and younger) and does so with less costs. Additionally my device is dramatically more affordable with an estimated production expense of less than one dollar for both product supply and assembly. It is disposable where most others are not thereby obviating the need for costly decontamination. This device is intended for use as an initial and primary intubating device for all attempted intubations and will greatly improve the success rate of initial attempts at intubation. Its unique design incorporating an endotracheal tube as a complete unit allows for faster introduction of the ET tube within the trachea and permits instantaneous technique conversion to "rescue intubation" when the patient's vocal cords can not be visualized. This convenient ability to convert techniques allows for more rapid and successful intubation by eliminating the need for having to withdraw the laryngoscope, ventilating the patient back up, re-executing laryngoscopy and then introducing another rescue device toward the objective anatomy.

Another version of my device may be used as part of an intubation system which is completely free of the need for decontamination and completely disposable. This version of my device achieves this by eliminating the current reliance on illumination from costly and problematic conventional laryngoscopes required by all other presently existing devices. This version of my device with only modest added expense incorporates on its most proximal end (the end inserted through the cords) an illuminating light source/lightbulb. This will not only provide the added anti perforation characteristics of the non illuminating version but will obviate the need for reliance upon lighted laryngoscope blades which are expensive and costly to maintain as well as potential sources of contagion. The light source on this version of the product is connected distally to a battery source and may be reused as a cost saving feature to the system while the rest of the device and plastic non illuminating laryngoscope blade are fully disposable. This second version permits rapid and numerous intubations of different patients limited only by the number of disposable devices and ET tubes available without any reliance on need for decontamination/sterilization processes currently now required. While compared to the non-illuminating version the illuminating feature of this version will add modest costs with a estimated manufacturing costs of still only approximately five dollars. It will still be disposable and ultimately considerably cheaper than presently existing intubation methods especially when the cost saved from avoiding sterilizing processes are considered.

In short, my device is simple to use, more effective in achieving first attempt intubations than other presently existing devices, completely disposable, with less risk for iatrogenic insult or injury and furthermore secures intubations with these added benefits more affordably than present devices. It has the potential, with time, for completely supplanting how all intubations are presently done with the widest of possible applications from the setting of controlled intubations in the OR, to the emergent intubation of an Emergency Room or field EMS setting. Its ease of use, and capacity for non-reliance on conventional laryngoscope blades which require sterilization, makes it ideally suited for the military combat medic. Safe intubations can now be quickly, easily and affordably obtained by medical personnel with even limited training through this device. It is likely with time that a method for safely and effectively achieving endotracheal intubations could be developed with this device alone through its blind but careful insertion into the paticats oral pharanx. It is clear this device has great potential and its warm reception from experienced physicians supports its predicted contributions in improving the paramountly important procedure of endotracheal intubation.

# DEPARTMENT OF THE ARMY
# UNITED STATES OF AMERICA
## INVENTION DISCLOSURE

PATENT ACTIVITIES DOCKET NO

(DRAWING AND DESCRIPTION SHEET)

(14) PROVIDE THE FOLLOWING INFORMATION CONCERNING THE DISCLOSED INVENTION AND IN THE INDICATED SEQUENCE:

A. SPECIFICALLY DESCRIBE THE INVENTION AND ITS OPERATION. YOU MAY USE AND ATTACH COPIES OF SKETCHES, PRINTS, PHOTOGRAPHS, PAPERS AND ILLUSTRATIONS, WHICH SHOULD BE SIGNED, WITNESSED, AND DATED. USE NUMBERS AND DESCRIPTIVE NAMES IN DESCRIPTIONS AND DRAWINGS.

B. STATE THE ADVANTAGES OF THE INVENTION OVER PRESENTLY KNOWN DEVICES, SYSTEMS, OR PROCESSES.

C. DISCUSS THE PROBLEMS WHICH THE INVENTION IS DESIGNED TO SOLVE, REFERRING TO ANY PRIOR INVENTION OF A SIMILAR NATURE WITH WHICH YOU MAY BE FAMILIAR.

D. LIST ALL KNOWN AND OTHER POSSIBLE USES FOR THE INVENTION.

E. LIST THE FEATURES OF THE INVENTION THAT ARE BELIEVED TO BE NOVEL.

USE AS MANY OF THESE SHEETS AS NECESSARY AND ATTACH TO COMPLETED INVENTION DISCLOSURE

See attached marked 14 (A) (B) ((D) incorporates C-E as well.

SIGNATURE(S) AND ORGANIZATION OF INVENTOR(S) (USE INK) DATE: THE DESCRIBED INVENTION HAS BEEN WITNESSED READ AND UNDERSTOOD BY: DATE:

(15) _____ (18) _____

ORGANIZATION

(16) _____ (19) _____

ORGANIZATION

(17) _____ (20) _____

ORGANIZATION

NOTE: THIS FORM AND ANY OMITTED INFORMATION BECOMING AVAILABLE AT A LATER TIME SHOULD BE FORWARD TO:
HQDA CHIEF, INTELLECTUAL PROPERTY DIV, OFFICE OF THE JUDGE ADVOCATE GENERAL DEPT. OF THE ARMY WASHINGTON, D.C., 20310
DARCOM ATTN: PATENT COUNSEL; OR CHIEF OF ENGINEERS ATTN: PATENT COUNSEL

REVERSE OF DA FORM 4734-R, 1 OCT 1978

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# INVENTION RIGHTS QUESTIONNAIRE

For use of this form, see AR 27-60; the proponent agency is OTJAG

## READ THE INSTRUCTIONS BELOW BEFORE COMPLETING THIS FORM

o Under Executive Order 10096, 23 January 1950, and AR 27-60, whenever an invention is made by a military or civilian employee of the Department of the Army, it is necessary to determine the rights in the invention as between the Government and the inventor. There are three ways in which rights may be determined:

– The inventor may be entitled to all rights and the Government to none (and hence the inventor need sign no document giving any rights to the Government);

– The Government may be entitled to a license permitting it to use or practice the invention and the inventor entitled to all other rights (and hence the inventor signs a license to the Government);

– The Government may be entitled to all rights and the inventor to none (and hence the inventor signs an assignment to the Government).

o Separate and distinct from the determination of rights, and even though it may appear that the inventor is entitled to all rights in the invention, the inventor may sign a license permitting the Government to use and practice the invention in return for which the Government will prosecute an application for a patent on the invention at no expense to the inventor, provided the Government is sufficiently interested in the invention.

o If the inventor desires voluntarily to assign all rights in the invention to the Government, he may complete PART A below. The remaining questions need not be answered.

o If the inventor does not desire to voluntarily assign all rights in the invention to the Government, it is necessary that all questions be answered completely. The determination of the rights in the invention depends upon the facts and circumstances under which the invention was made. In almost every case a failure to provide sufficient information works to the disadvantage of the inventor. If additional space is needed to fully answer any question, an attached sheet will be used. Many questions may be answered by a check mark; however, every question must be answered even if the appropriate answer is "No", "None", or "NA"(not applicable). Print or type all answers.

## SECTION I - TO BE COMPLETED BY THE INVENTOR

### PART A - BASIC DATA

1 BRIEF TITLE OF INVENTION

2. NAME OF INVENTOR

3 GRADE AT TIME INVENTION WAS MADE

4. JOB TITLE AT TIME INVENTION WAS MADE

5. COMPLETE NAME OF ORGANIZATION AT TIME INVENTION WAS MADE *(Include, as applicable, unit, section, branch, division, department, laboratory, post, camp, station, branch of Army)*

6. I DESIRE TO ASSIGN TO THE UNITED STATES GOVERNMENT THE ENTIRE RIGHT, TITLE AND INTEREST IN AND TO THE [illegible]TIED INVENTION. *(Signature below is necessary only if assigning rights of invention to the Government. The remainder of this form is not necessary if you sign below.)*

a. SIGNATURE OF INVENTOR

b. DATE

DA FORM 2871-R, APR 93

REPLACES DA FORM 2871, JAN 65 WHICH IS OBSOLETE

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